

Europäisches Patentamt

European Patent Office

Office européen des brevets



(11) EP 0 706 355 B1

(12)

ie.

EUROPEAN PATENT SPECIFICATION

- (45) Date of publication and mention of the grant of the patent:05.03.1997 Bulletin 1997/10
- (21) Application number: 94920414.3
- (22) Date of filing: 29.06.1994

- (51) Int. CI.⁶: **A61F** 5/453 // A61M25/02
- (86) International application number: PCT/DK94/00267
- (87) International publication number: WO 95/01143 (12.01.1995 Gazette 1995/03)
- (54) EXTERNAL URINARY CATHETER
 EXTERNER URINALKATHETER
 CATHETER URINAIRE EXTERNE
- (84) Designated Contracting States:
 AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL
 PT SE
- (30) Priority: 02.07.1993 DK 794/93
- (43) Date of publication of application: 17.04.1996 Bulletin 1996/16
- (73) Proprietor: COLOPLAST A/S DK-2980 Kokkedal (DK)
- (72) Inventor: TANGHÖJ, Allan DK-2000 Frederiksberg C (DK)

- (74) Representative: Raffnsöe, Knud Rosenstand Internationalt Patent-Bureau,
 23 Höje Taastrup Boulevard
 2630 Taastrup (DK)
- (56) References cited:

DE-A- 221 533

DE-A- 520 401 US-A- 4 388 923

GB-A- 2 126 483 US-A- 4 640 688

 Encyclopedia of Polymer Science and Engineering Vol 15, 1989

P 0 706 355 B1

THE TENNET OF THE SECOND PROPERTY OF THE PROPE

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

reduced because the skin contact is restricted to the extreme portion of glans and the foreskin, and because no adhesive fastening is used.

Likewise the application is simpler because the catheter does not need to be unrolled, and the possibilities of use of the catheter are thus also less dependent on the size of penis.

In relation to the prior art catheter according to above GB patent application there is first and foremost obtained a substantially less disturbing position without the risk of tissue damage as a result of only the extreme portion of glans being covered by the inner catheter member.

Thereby, the possibility is further obtained that the catheter according to the invention may be manufactured as a "one-size" product, which considerably reduces the cost of storage and thus makes the production less expensive.

The improved form stability in the area at the transition to the discharge spout entails that the catheter member through a suitable outer shape may be produced with a sufficient security against falling off in use due to a pull or compressive load.

This advantage is particularly obtained by a preferred embodiment, in which the catheter further comprises an outer holder member for fastening the catheter member in the state of use, and which is characterized in that the outer holder member is a separate member <u>enveloping</u> the discharge spout of the inner catheter member, and may be <u>displaced</u> axially in relation thereto.

The separate outer holder member placed on the discharge spout is after arrangement of the catheter member under the foreskin pressed to abut on the outer side of the extreme part of the foreskin. This provides for obtaining a particularly reliable fastening with no substantial inconveniences to the user, since a load in the form of a pull at the discharge spout, e.g. due to the weight of the urine collection bag connected with the discharge spout, or a compressive load from the urine instead of involving the risk that the catheter falls off, entails an improvement of the fastening of the foreskin between the catheter member and the outer holder member.

The invention will now be explained in detail with 45 reference to the schematical drawings, in which

Figs. 1 and 2 show a sectional view of a preferred embodiment of the catheter according to the invention, with and without the outer holder member, respectively,

Fig. 3 the catheter shown in Fig. 1 in an applied condition, and

Figs. 4 to 8 show differently modified designs.

The example shown in Fig. 1 of an external urinary catheter according to the invention comprises an inner catheter member 1 and a tubular discharge spout 2 intended for connection of the catheter with a hose, not

shown, leading to a urine collection bag that may be of a known design.

The catheter member 1 and the discharge spout 2 are manufactured in one piece, e.g. by injection moulding of thermoplastic elastomeric material.

The catheter member 1, which as shown in Fig. 2 in the state of use is intended to be placed under the foreskin 3 in contact with the head or glans 4 of penis, has according to the invention such a short axial extent, e.g. 5 to 35 mm, that in use it only covers the extreme portion of glans outside the point where glans has its largest diameter.

It is thereby prevented, that the catheter member 1 in the state of use is placed with its end edge 5 against the sensitive skin band between glans and foreskin.

At the transition to the discharge spout 2 the in itself elastically resilient catheter element 1 is designed with such a form stability that in use it preserves its outer shape at the place where the catheter member is fastened by the extreme portion of the foreskin 3.

In the embodiment in Fig. 1 to 3 the increased form stability at the transition between the catheter member 1 and the discharge spout 2 is obtained in a simple manner in that the catheter member 1 is designed with an increased wall thickness in this local area.

The illustrated catheter member 1 is thus designed with an almost bowl-shaped profile, where a substantially plane outer surface 6 is provided about the discharge spout 2 substantially perpendicular to the discharge spout 2, whereas the side wall of the bowl-shaped profile is formed by a skirt portion 7, which joins the outer surface 6 via a shoulder-like ledge 8.

The internal side of the catheter member 1 constitutes an arched bowl-shaped bottom face 9 fitting to the shape of the extreme portion of glans 4.

The application is effected in that the catheter member 1 with the foreskin 3 retracted is placed against glans 4, the discharge spout being placed opposite the mouth of urethra, after which the foreskin 3 is passed out and around the catheter member 1 and fastens this in that the slightly stretched foreskin presses against the outer surface 6.

Practical tests have shown that by virtue of the elasticity of the foreskin 3 in itself and the increased form stability at the transition between the catheter member 1 and the discharge spout 2 a surprisingly good fastening of the catheter member 1 is obtained in the state of use, even with no further arrangements.

Thus, inter alia patients confined to bed can often make use of the catheter with sufficient security without the separate holder member that will be described in the following.

Even though the catheter member 1 as already mentioned in many cases can be used alone an outer holder member 10 may be used to obtain an additionally secure fastening, said member being manufactured as a separate member with a tubular part 11 enveloping the discharge spout 2 but not narrower than it can be displaced axially thereon, possibly in connection with a

5

30

35

45

side (26).

 An external urinary catheter according to claim 3, 4 or 5, characterized in that the outer holder member (10, 14, 28) is substantially bowl-shaped.

Patentansprüche

1. Externer Urinalkatheter zum Abhelfen von Urininkontinenz bei Männern und von der Art umfassend eine Ausgusstülle (2) zum Anschluss an einen Schlauch und ein damit integriert verbundenes Katheterelement (1) mit einer kurzen axialen Länge und einer der Form der Eichel (Glans) eines Penis angepassten inneren Kontaktfläche, welches Katheterelement bei Gebrauch unter der Vorhaut angebracht werden kann und in dieser Lage in Oberflächenkontakt mit der Eichel (Glans) (4) steht und nur den äussersten Teil der Eichel an der Stelle, wo diese ihren grössten Durchmesser aufweist, deckt, dadurch gekennzeichnet, dass das Katheterelement (1) aus thermoplastischem, élastomerem Material hergestellt und im Bereich des Übergangs zur Ausgusstülle (2) mit Mitteln ausgebildet ist, die der Aussenseite des Katheterelements eine Formstabilität verleihen, um dieses allein durch die mit der Aussenseite in Berührung kommende Vorhaut (3) in Kontakt mit der Eichel (Glans) (4) festzuhalten, und dass die Mittel

einen bei einer im wesentlichen ebenen Anlagefläche (6) des Katheterelements (1) herum und zur Ausgusstülle im wesentlichen senkrecht verlaufenden schulterähnlichen Absatz (8). oder

eine oder mehrere an der Aussenseite des Katheterelements (13) zirkular verlaufende Rippen (16), <u>oder</u>

einen in einem im wesentlichen schalenförmigen Katheterelement (27) eingebetteten, zirkularen Absteifring (30), <u>oder</u>

einen bei erwähntem Übergang erhobenen Schulterabschnitt (21), oder

eine beliebige dieser Kombinationen umfassen.

 Externer Urinalkatheter nach Anspruch 1, dadurch gekennzeichnet, dass das Katheterelement (17) an seiner proximalen Endkante mit einer nach innen verlaufenden, verhältnismässig weichen 50 Dichtungslippe (19) versehen ist.

Externer Urinalkatheter nach Anspruch 1 oder 2
und ferner umfassend ein äusseres Halteelement
(10) zum Festhalten des Katheterelements (1) in
der Gebrauchsstellung, dadurch gekennzeichnet,
dass das äussere Halteelement (10) ein separates
Element ist, das die Ausgusstülle (2) des inneren
Katheterelements umschliesst, aber im Verhältnis

zu diesem axial verschiebbar ist.

- Externer Urinalkatheter nach Anspruch 3, dadurch gekennzeichnet, dass das äussere Halteelement (26) mit einer an die Aussenseite des Katheterelements (20) angepassten Innenfläche ausgebildet ist.
- Externer Urinalkatheter nach Anspruch 3 oder 4, dadurch gekennzeichnet, dass das äussere Halteelement (25) um die Ausgusstülle herum als ein Kragenteil mit einer im wesentlichen ebenen Unterseite (26) ausgeformt ist.
- Externer Urinalkatheter nach Anspruch 3, 4 oder 5, dadurch gekennzeichnet, dass das äussere Halteelement (10, 14, 28) im wesentlichen schalenförmig ist.

Revendications

1. Cathéter urinaire extérieur pour le soulagement à l'incontinence d'urine des hommes et du type comprenant une goulotte (2) de décharge à être reliée à un tuyau et intégralement reliée à un élément (1) de cathéter ayant une étendue axiale courte, et une surface intérieure de contact adaptée à la forme de la tête (du gland) d'un pénis de manière à pouvoir être arrangée, en usage, dans une position au-dessous du prépuce et dans laquelle elle est en contact de surface avec la tête (le gland) (4) pour ne couvrir que la partie extrême de la tête en dehors du point où le gland présente son diamètre le plus large, caractérisé en ce que l'élément (1) de cathéter est fait d'un matériau thermoplastique et élastomérique et, dans l'endroit à la transition vers la goulotte (2) de décharge, est formé avec des moyens pour pourvoir une stabilité de forme à son côté extérieur afin de rester en contact avec le gland (4) uniquement au moyen du prépuce (3) s'appuyant sur ledit côté extérieur, lesdit moyens comprenant

une saillie (8) semblable à une épaule à une face (6) d'appui de l'élément (1) de cathéter essentiellement plane arrangée autour de et essentiellement perpendiculaire à la goulotte de décharge, ou

une ou plusieurs nervures (16) circonférentielles au côté extérieur de l'élément (13) de cathéter, ou

une bague (30) de renforcement circonférentielle et incrustrée dans un élément (27) de cathéter essentiellement en forme d'une coupe, <u>ou</u>

une portion (21) d'épaule dressée à ladite transition, <u>ou</u> une combinaison quelconque desdits moyens.

2. Cathéter urinaire extérieur selon la revendication 1,

5

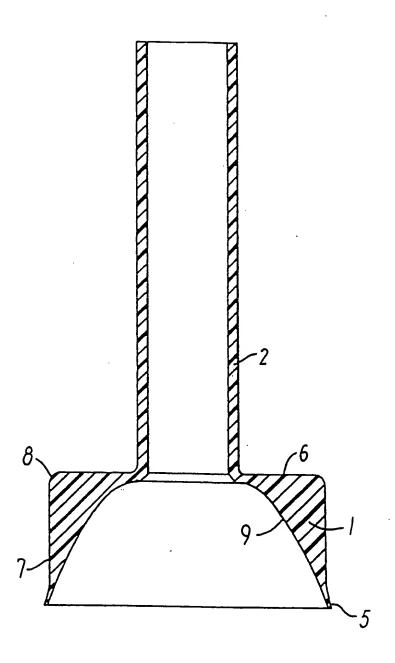


FIG.1

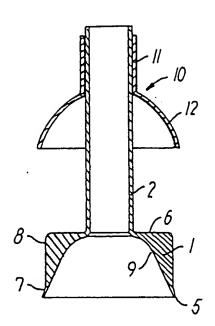
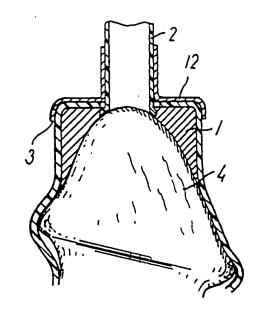


FIG. 2



F1G.3

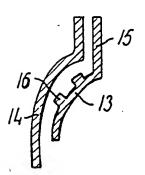


FIG. 4

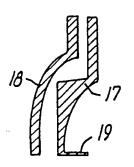


FIG.5

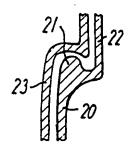
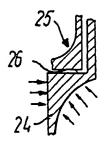


FIG.6



FIĢ.7

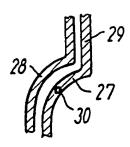


FIG. 8